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TITLE:
Treatment of Early Post-op Wound Infection after Internal Fixation

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14. ABSTRACT

Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to (1) evaluate the effect of treatment of post-op wound infection in long bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after fixation of fractures or joint fusion.

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Nothing Listed

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Annual Report: "Treatment of Early Post-Op Wound Infection after Internal Fixation" Sept. 15, 2015 - Sept. 14, 2016

Introduction:

Severe fractures are common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation develop a deep wound infection during the healing process. Thus, the overall goals of this study are to investigate the efficacy of oral (per os, (PO)) antibiotic therapy versus intravenous (IV) antibiotics in the treatment of acute infection after fixation of fractures or fusion of joints.

Study Specific Aim # 1: To evaluate the effect of treatment of post-op wound infection in bones after fracture fixation or joint fusion and either: (Group 1) operative debridement and PO antibiotic treatment for 6 weeks; or (Group 2) operative debridement and IV antibiotics for 6 weeks.

Study Specific Aim # 2: To build and validate a risk prediction model for failure of treatment of early post-op wound infections after fixation of fractures and joint fusions.

Body:

During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to recruitment and enrollment into the study. As of October 1, 2016, a total of 1143 patients have been screened for eligibility, and of these, 503 were eligible. Of the 503 eligible patients, 128 (25% of eligible) were consented and enrolled into the RCT; 87 (17% of eligible) were consented and enrolled into the observational arm. We have now reached 48.5% of our total enrollment. Seventy-five patients have completed the study.

Task 1	Months 1-6	Completed
Task 2	Months 6-72	Completed
Task 3	Months 12-84	Enrollment – in progress
Task 4	Months 48-84	Complete Follow up visits- in progress
Task 5	Months 84-96	Conduct analysis and final report- in progress

NEXT STEPS:

- Continue enrollment through September 2017.
- Complete follow up visits by September 2018.
- Begin data analysis once we reach 50% of enrollment goal as per protocol
- Encourage each site to enroll 6 patients over the next 12 months to meet enrollment goals
- Develop reports related to project deliverables for Consortium

Key Research Accomplishments:

- We have reached 48.5% of our enrollment goals
- 75 patients have completed the study
- The implementation of the observation arm has increased our enrollment rate.

Reportable Outcomes:

There were 32 serious adverse events (SAEs) reported during this reporting period.Twenty-six events were related to abnormal laboratory results and each determined by the medical monitor to be unrelated to study participation. Two patients experienced worsening/new infections. The remaining four consisted of allergic reaction, thrombosis of PICC line, exostosis and erythema. The medical monitor reviewed all SAEs and determined that no further action was required.

Conclusion:

None

References:

None

Appendices:

N/A